ALSIUS CORPORATION

Section 4: 510(k) Summary

510(K) Summary: Alsius Corportation's CoolGard™ / Cool Line™ Catheter Thermal Regulation System

Submitter's Name, Address, Telephone Number, and Contact Person:

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AUG 01 2003

Contact: Ken Collins
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Name of Device:

The Alsius CoolGard And Cool Line Catheter Thermal Regulation System.

Common or Usual Name:

Central Venous Catheter (short term) and Thermal Regulating System.

Classification Name:

Venous heat exchange catheters and associated temperature control systems have not been specifically classified by the FDA. However, FDA has classified venous catheters and thermal regulating systems as Class II devices under 21 C.F.R. §§ 880.5200 and §§ 870.5900 respectively.

Predicate Device(s):

Alpha Omega Dual Cooler Heater;
Alpha Omega, Inc., Austin TX
K001520; S.E. 11-22-2000

MTRE Allon 2001 Thermal Regulation Device;
MTRE Advanced Technologies, McCordsville, IN
K001546; S.E. 06-08-2000

ARROWgard Blue Quad-Lumen Central Venous Catheter
Arrow International, Inc., Reading PA
K962577; S.E. 08-21-1997

Arrow-Howes Large Bore Multi Lumen central venous catheter
Arrow International, Inc., Reading PA
K970864; S.E. 09-17-1997

Indications for Use

The Alsius CoolGard® 3000 and Cool Line ™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrchnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results please refer to "Physician's Manual – Fever Reduction for Patients with Cerebral Infarction and Intracerebral Hemorrhage" #101416-001.

Technical Characteristics:

The CoolGard and Catheter Thermal Regulation System consists of the CoolGard™ 3000, a disposable Start Up Kit used in the CoolGard™ for interface with the cooling bath and patient catheter and the Intravascular Catheter. The Alsius CoolGard™ 3000 is an integrated electro-mechanical heater/cooler that consists of a temperature monitor, a temperature controller unit, a heat exchanger unit, and roller pump. It supplies temperature controlled sterile saline to the indwelling Catheter that is placed percutaneously in the patient.

The technical characteristics of the Catheter are essentially identical to those of widely used multi-lumen central venous catheters except for the dedicated closed loop fluid path through the heat exchange balloons. The Alsius Catheter materials are all biocompatible polyurethanes.

Likewise, the CoolGard™ 3000 heater/cooler has the same technical features as the medical heater/cooler unit Identified as the predicate device. These common technical features include connections for recirculating coolant to and intravascular catheter and all or combinations of the following: redundant safety controls and alarms, patient monitoring and control and temperature displays for the clinician users.

Two Models of Intravascular catheters are available for use with the CoolGard and Catheter Thermal Regulation System:

1. Cool Line™ Catheter Kit Model CL 2085B (2 lumens)
2. Cool Line™ Catheter Kit Model CL 2295A (3 lumens)

The Cool Line™ catheters are multi lumen intravascular catheters in two sizes. Two of the catheter's lumens are used to circulate sterile saline to exchange heat with the central venous blood supply. When the heat exchange feature of the catheter is in use, heated/chilled saline is pumped through the heat exchange lumen, expanding the diameter of the distal portion of the catheter to a nominal 5mm where the heating/cooling membranes interface with the patient's circulating blood. The inflow lumen/outflow lumen forms a closed-loop system through which the heated/chilled saline circulates. The chilled saline is not infused into the patient.

Additional lumens of the Alsius Catheters consist of a standard guide wire lumen that can be used as a primary infusion lumen, and a second or third infusion lumen within the shaft, depending on the catheter model selected by the clinician.

The Catheter blood contact surfaces are coated with Duraflo® Treatment, a heparin coating manufactured by Edwards Lifesciences Corporation.

The Alsius Catheters are supplied sterile for single-use only.

Principles of Operation:

The CoolGard™ 3000 system automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via data from a temperature probe in the patient that

interfaces with the temperature controller. This principle of operation is identical to currently marketed devices.

Summary of the Basis for Finding of Substantial Equivalence:

The Cool Line™ indication statements and intended use are identical to those for central venous catheters and heater/cooler units. The Cool Line™ catheter provides access to the central circulation for fluid administration. Additionally, the closed loop connections on the catheter can be attached to the heater/cooler unit for patient heating or cooling via conductive heat transfer from the temperature controlled saline. The Cool Line™ integrates venous access and temperature control which, separately, are intended uses for numerous devices.

The integration of temperature control and venous access could potentially affect safety and effectiveness in new ways that would raise new types of safety or effectiveness questions. Accepted scientific methods were used to generate performance data demonstrating the substantial equivalence of the Cool Line™ Catheters and CoolGard™ System to the predicate. In addition, the clinical study under IDE G990263 was conducted to further define safety characteristics.

Conclusion

In summary, descriptive information and performance data demonstrate that the Alsius Cool Line™ Catheter and CoolGard™ System's different technological characteristics either do not raise new questions of safety and effectiveness or, where appropriate, performance data demonstrate equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Kenneth A. Collins, M.D.
Vice President Clinical/Quality/Regulatory
Alsius Corporation
15770 Laguna Canyon, Road, Suite 150
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Re: K014241
Trade/Device Name: Alsius CoolGard and Cool Line Catheter Thermal Regulation System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NCX
Dated: June 20, 2003
Received: June 20, 2003

Dear Dr. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling as a box warning immediately following the indications for use statement:

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

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For more details on the results of this study please refer to "Physician's Manual – Fever Reduction for Patients with Cerebral Infarction and Intracerebral Hemorrhage" #101416-001.

Please note that the above labeling limitation is required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before this limitation is modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers,

International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014241

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Alsius CoolGard 3000/Cool Line Catheter Heat Exchange System

Indications for Use

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Prescription Use [X]

Over the Counter [ ]

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____